

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
AT CLARKSBURG**

TAKEDA GMBH, ASTRAZENECA
PHARMACEUTICALS LP, and
ASTRAZENECA UK LIMITED,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS INC.,

Defendant.

C.A. No. 1:15-CV-00093-IMK

**MYLAN PHARMACEUTICALS INC.'S
OPPOSITION TO PLAINTIFFS' MOTION TO STAY**

Defendant Mylan Pharmaceuticals Inc. (“Mylan”) respectfully opposes Plaintiffs Takeda GmbH, AstraZeneca Pharmaceuticals LP, and AstraZeneca UK Limited’s (collectively, “Plaintiffs”) Motion to Stay (“Motion”).

I. INTRODUCTION

Plaintiffs request for a stay in favor of its first-filed New Jersey action or until the Federal Circuit resolves the pending jurisdictional issues should be denied. In New Jersey, Mylan has strenuously disputed jurisdiction and, importantly, the New Jersey court *has not yet resolved the jurisdictional issue*. The New Jersey action will not proceed until the court does so. And although Mylan’s interlocutory appeals on a similar issues are pending before the Federal Circuit, the cases have not yet been scheduled for oral argument, the court has not indicated when it will rule—and there is no way to predict when it will do so.

This Court recently has denied similar stay requests in several recent cases where the other district had not yet ruled on Mylan’s motion to dismiss. *Novartis Pharms. Corp. v. Mylan*

Inc., No. 1:14-cv-106, Order (D.I. 47) at 15 (N.D.W. Va. Jan. 27, 2015); and *Novartis Pharms. Corp. v. Mylan Inc.*, No. 1:14-cv-111, Order (D.I. 38) at 15 (N.D.W. Va. Jan. 29, 2015).

Plaintiffs should not be permitted to forum shop and unnecessarily tie up the Court's docket merely as a "backup plan" in the event they are unable to litigate in New Jersey. There is no just cause to delay this action. Accordingly, Plaintiffs' Motion should be denied.

II. FACTUAL BACKGROUND

A. The District of New Jersey Action

Plaintiffs sued Mylan in the United States District Court for the District of New Jersey for infringement of four patents based on Mylan's filing of an Abbreviated New Drug Application ("ANDA") a generic roflumilast product on May 15, 2015. *See* Ex. 1 ("New Jersey complaint"). Plaintiffs sued nine other defendants in the same jurisdiction. All of these cases are in their infancy: six defendants recently answered and three defendants have been granted extensions to respond. Mylan moved to dismiss the New Jersey complaint for lack of personal jurisdiction on June 24, 2015. Plaintiffs invoked their right under the local rules to an automatic extension and filed their response on Monday, July 20. Mylan filed its reply on July 27. That motion is pending.

Mylan has not filed an answer or otherwise participated in the New Jersey action for any purpose other than the motion to dismiss. The New Jersey court has not set a date for a scheduling conference.

B. This Action

Plaintiffs filed a complaint in this Court, alleging infringement of the same patents asserted and on the same grounds as in the New Jersey on May 27, 2015. D.I. 1. Mylan filed its Answer and Counterclaims on June 26, 2015. D.I. 8. Plaintiffs filed their answer to Mylan's counterclaims on July 17, 2015. D.I. 12.

No further pleadings are expected, and Mylan stands prepared to serve written discovery at the earliest opportunity.

III. ARGUMENT

Plaintiffs' request for a stay should be denied because they have not met their burden to "justify [a stay] by clear and convincing circumstances outweighing potential harm to the [non-moving] party" and "make out a clear case of hardship or inequity in being required to go forward." *Williford v. Armstrong World Indus., Inc.*, 715 F.2d 124, 127 (4th Cir. 1983) (internal quotations omitted).

A. The First-to-File Rule Does Not Apply

Plaintiffs rely on the "first-to-file" rule to argue that this action should be stayed merely because they sued in District of New Jersey a few days earlier than in this District.

Under the first-to-file rule, when two courts have concurrent jurisdiction in substantially identical cases, the court hearing the second-filed action may defer to the court hearing the first-filed action. *See, e.g., Novartis*, No. 1:14-cv-106, Order (D.I. 47) at 7-8. The rule is subject to several exceptions, including consideration of the balance of convenience, and whether the suit was filed in bad faith, or whether the suit was filed for the purposes of forum shopping. *Id.* at 9 (citations omitted).

The first-to-file rule does not apply here for at least three reasons: First, there is a serious, ongoing and unresolved dispute about the New Jersey court's person jurisdiction over Mylan. Second, Plaintiffs appear to be forum shopping, which precludes the application of the first-to-file rule. Finally, this action is more advanced than the New Jersey action and is likely to stay so.

1. Jurisdiction is Unsettled and Sharply Contested in the New Jersey Action

The first-to-file rule does not apply where, as here, jurisdiction in the parallel litigation is unsettled and vigorously disputed, and the first-filed case is not progressing. *Genentech, Inc. v. Eli Lilly & Co.*, 998 F.2d 931, 938-39 (Fed. Cir. 1993); *Boehringer Ingelheim Pharma GmbH & Co., et. al. v. Mylan Pharmaceuticals, Inc.*, No. 1:15-cv-10, Order (D.I. 37) at 7 (N.D.W. Va. Mar. 27, 2015).

Plaintiffs appeal to the general notion that a plaintiff should be entitled to select its forum, but that rationale is, of course, meaningless when the forum of choice does not have personal jurisdiction over the defendant. *See* Motion at 9.

In a considering motions to stay in cases like this one, this Court found the reasoning of *Genentech* persuasive and acknowledged that a serious unresolved jurisdictional dispute in the first-filed action supports denial of a stay of the second. Compare *Novartis*, No. 1:14-cv-111, Order (D.I. 38) at 11, 14 (denying motion to stay) and *Novartis*, No. 1:14-cv-106, Order (D.I. 47) at 11, 13 (same) with *Acorda Therapeutics, Inc. v. Mylan Pharmaceuticals Inc.*, No. 1:14-cv-139, Order (D.I. 59) at 9 (N.D.W. Va. Feb. 11, 2015) (noting *Novartis* cases were not stayed “where jurisdiction in the first-filed action was vigorously disputed and the case was not progressing”, but granting stay where district court had ruled on first-filed jurisdictional dispute and first-filed motion to stay, and case was progressing).

This case is on all fours with this Court’s two recent *Novartis* decisions denying similar motions to stay. Just as here, the New Jersey district court has not decided Mylan’s motion to dismiss, and Mylan could be “faced with the possibility of both a stay in this case and a long wait in the District of [New Jersey] should that court choose to withhold its decision on Mylan’s motion to dismiss until the Federal Circuit decides the interlocutory appeal [to the Federal

Circuit] in AstraZeneca [AB v. Mylan Pharma Inc., No. 1:14-cv-696-GMS (D. Del. Nov. 5, 2014)].” *Novartis*, No. 1:14-cv-111, Order (D.I. 38) at 14; contrast with *Novartis*, No. 1:14-cv-111, Order (D.I. 75) at 9 (granting renewed motion to stay where the filed-filed court ruled on Mylan’s motion to dismiss and was proceeding at a rapid pace).¹

In contrast to the decision granting a motion to stay in the *Acorda*² case, Plaintiffs’ first-filed case is at a standstill. Mylan, and three other defendants in related cases, have not even filed answers to Plaintiffs’ complaints.

Thus, due to the unresolved serious jurisdictional dispute and lack of progression in the New Jersey action, the first-to-file rule does not apply to this case and should not be used as a basis to stay the action.

2. Plaintiffs’ Forum Shopping Bars the First-To-File Rule

Even if first-to-file rule applied, the Court should still deny Plaintiffs’ Motion because several of rule’s exceptions apply. “The first-to-file rule is subject to various exceptions, including consideration of whether the balance of convenience weighs in favor of the second-filed court’s continued exercise of jurisdiction over the suit, whether the suit is filed in bad faith, or whether the suit is filed for the purpose of forum shopping.” *Novartis*, No. 1:14-cv-106, Order

¹ Plaintiffs mischaracterize this Court’s ruling in *Norvartis*, No. 1:14-cv-00106, Order (D.I. 87) at 10. Motion at 6 n.4. In *Norvartis*, Plaintiffs renewed their motion to compel after Judge Andrews in Delaware decided some of the jurisdictional issues and had “chosen to proceed with the case” in the face of other jurisdictional challenges. Order (D.I. 87) at 9-10. This Court found it compelling that the first-filed suit was proceeding at a rapid pace, and had even been scheduled for trial. This is not the case here.

² The Federal Circuit has granted Mylan’s requests for interlocutory review in two cases, *Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, No. 15-1456 (Fed. Cir.) and *AstraZeneca AB v. Mylan Pharm. Inc.*, No. 15-1460 (Fed. Cir.). Both appeals seek reversal of the denial of Mylan’s motions to dismiss for lack of personal jurisdiction in Delaware. *Id.*

(D.I. 47) at 9 (citing *EEOC v. Univ. of Pa.*, 850 F.2d 969, 976 (3d Cir. 1988); *Ellicott Mach. Corp. v. Modern Welding Co.*, 502 F.2d 178, 181 (4th Cir. 1974)).

First, although the first-filed court typically determines whether convenience favors the second-filed court's continued exercise of jurisdiction over the suit, here there is no parallel motion to stay in New Jersey. *Id.* (citing *Touchstone Research Lab, Ltd. v. Anchor Equip. Sales, Inc.*, 294 F. Supp. 2d 823, 828 (N.D.W. Va. 2003)). Nonetheless, the convenience factor strongly favors the continued progression of this action. This action is well underway, whereas Mylan has not filed an answer in the New Jersey action. Thus, the parties should continue to pursue this action in order to prevent needless and prejudicial delay of resolution of the dispute. As practical matter, should the district court in New Jersey ultimately be found to have jurisdiction, any progress made in this Court may be transferred to that action.

Second, Plaintiffs' attempt at forum shopping creates a further exception to the first-to-file rule.³ None of three plaintiff entities are either incorporated in or has a principal place of business in New Jersey. Complaint (D.I. 1) at ¶¶ 3-5. Although Mylan is at home in West Virginia, it too, is a stranger to New Jersey. Ex. 1 (New Jersey Complaint) at ¶ 7; Complaint (D.I. 1) at ¶ 7. Nevertheless, Plaintiffs selected the District of New Jersey. Thus, Plaintiffs are seeking to litigate in a forum they hope will be advantageous. Mylan seeks only to litigate in a forum where its constitutional due process rights will not be violated by the exercise of jurisdiction over it. Plaintiffs' attempt at forum shopping provides an exception to the first-to-file rule and should not be indulged.

³ Plaintiffs' accusation that Mylan has unilaterally undertaken to undermine Plaintiffs' choice of forum is puzzling given that *Plaintiffs* elected to file suit in multiple fora, and *Plaintiffs* selected the particular fora in which to file. *See* Motion at 9-10. That Mylan took the time to evaluate the circumstances and object to having its rights adjudicated in a state which lacks personal jurisdiction over it cannot fairly be deemed "forum shopping."

3. The Prerequisites for the First-to-File Rule Are Not Met

The first-to-file rule also does not support a stay because the prerequisites are not met in this case. Courts typically consider three factors in determining whether the first-to-file rule applies: (1) chronology; (2) identity of parties; and (3) similarity of issues. *See, e.g., Novartis, No. 1:14-cv-111, Order (D.I. 38) at 7-8 (citing Intersearch Worldwide, Ltd. v. Intersearch Group, Inc., 544 F. Supp. 2d 949, 957 (N.D. Cal. 2008))*. Here, the New Jersey action was filed before this action, but this action is in a more advanced stage. In this action, the pleadings are settled and the parties are awaiting notice of a Rule 16(b) conference. In New Jersey, the pleadings are not settled and jurisdiction is seriously disputed.

Moreover, the issues involved in this action are not identical. In this action, Mylan has filed counterclaims alleging that the asserted patents are invalid. In the interests of efficiency, Mylan aims to propound discovery related to these claims as soon as is possible. In contrast, Mylan has yet to answer the New Jersey complaint, asserted no counterclaims, and has not yet served discovery. In fact because Mylan has not raised the issue of patent invalidity in New Jersey, Mylan cannot pursue discovery on this issue. Thus, currently this Court provides the only forum in which Mylan can seek evidence in support of its claims.

B. The Court Should Decline Plaintiffs' Invitation to Delay Resolution of this Dispute

Plaintiffs also attempt to appeal to the Court's broad discretionary power to manage its docket in support of their request to stay this action in favor of the New Jersey action or while the Federal Circuit decides Mylan's pending interlocutory appeal. *See Landis v. N. Am. Co.*, 299 U.S. 248, 254 (1936). However, the relevant circumstances weigh decidedly in favor of allowing this action to proceed while the New Jersey district court and the Federal Circuit resolves the jurisdictional issues. In general, courts consider three factors in ruling on a motion to stay: (1)

the interests of judicial economy; (2) hardship and equity to the moving party if the action is not stayed; and (3) potential prejudice to the non-moving party. *Novartis*, No. 1:14-cv-111, Order (D.I. 38) at 10. As in *Novartis*, each of these factors weighs against a stay in this case.

1. The Interests of Judicial Economy Favor Proceeding With This Action

A stay of this action would be counter to interests of judicial economy, because this action has progressed significantly further than the New Jersey action—which is not progressing at all—and Mylan will likely serve discovery related to its counter-claims in this action. Even if the Court later transfers this suit to the District of New Jersey, “it can resolve and discovery disputes and move the lawsuit along in the interim.” *Id.* at 14.

Ultimately, it is likely that the New Jersey action will be dismissed as to Mylan for lack of personal jurisdiction. Plaintiffs argue that allowing this action to proceed would result in duplicative litigation or inconsistent rulings, but that is not correct, as this action will only proceed in parallel with the New Jersey action until the jurisdictional dispute is resolved—thus, there is no danger of duplicative litigation.

Moreover, if the Court were to grant a stay, the 30-month stay of regulatory approval would continue to run despite the parties’ inability to pursue resolution of the case. 21 U.S.C. § 355(j)(5)(B)(iii)(III). This would greatly increase the chance that the 30-month stay would expire during the pendency of the action and that Plaintiffs would file a motion for preliminary injunction, resulting in further wasted time and needless expense of judicial resources. On the other hand, if the Court denies a stay, the litigation may proceed in an efficient and expeditious manner. If the District of New Jersey ultimately determines it has personal jurisdiction over Mylan, this case may be transferred to New Jersey such that the parties and that court need not

start from scratch, thereby further serving the interests of judicial economy.⁴ *See Novartis*, No. 1:14-cv-111, Order (D.I. 38) at 14. Accordingly, the interests of judicial economy would be best served by denying a stay.

2. Plaintiffs Will Not Suffer Hardship If This Action Is Not Stayed

Plaintiffs cannot complain of prejudice as a result of proceeding with litigation in a forum that they chose. In fact, Plaintiffs' primary complaint appears to be that it would be "forced to litigate against Mylan" in multiple forums while maintaining other actions against nine other defendants Plaintiffs initiated. Motion at 13. But if this truly Plaintiffs' concern—and if they truly view New Jersey as is a proper place to litigate and one chosen for strategic purposes—then Plaintiffs should dismiss this action entirely. *Boehringer Ingelheim Pharma GmbH & Co., et. al. v. Mylan Pharmaceuticals, Inc.*, No. 1:15-cv-10, Order (D.I. 50) at 2 (N.D.W. Va. June 2, 2015) (questioning why, with jurisdictional issues in the first-filed case resolved, plaintiffs sought to stay as opposed to dismiss the second-filed lawsuit).

Plaintiffs' unilateral request to stay this case is irreconcilable with their statutory duty to reasonably cooperate in expediting the litigation they initiated. See 21 U.S.C. § 355(j)(5)(B)(iii). Indeed, given that the New Jersey action will not progress as to Mylan before resolution of the jurisdictional dispute, resources will not be wasted if the parties continue to litigate this action while the jurisdictional dispute is being resolved. Moreover, as noted, if the District of New Jersey eventually finds that it has jurisdiction over Mylan, this Court may transfer the case to New Jersey. *Novartis*, No. 1:14-cv-111, Order (D.I. 38) at 15. Thus, permitting this action to

⁴ Plaintiffs' argument to the contrary—that denial of a stay would waste judicial resources—lacks merit. In support of this argument, Plaintiffs cite *Novartis AG v. Ezra Ventures, LLC*, No. 4:15-CV-00095 KGB, 2015 WL 4197692 (E.D. Ark. July 10, 2015), a case where the first-filed court had already decided issues of personal jurisdiction.

continue will not harm Plaintiffs and is in fact the most efficient manner for the parties and the Court to proceed.

3. Mylan Will Be Severely Prejudiced If This Action Is Stayed

Mylan will be greatly prejudiced if this action is stayed pending resolution of the jurisdictional dispute in New Jersey. A stay in this case would have the likely effect of pushing final resolution beyond the expiration of the 30-month stay, likely provoking a motion for preliminary injunction—an exercise which consumes judicial resources and causes great expense to the parties.

Plaintiffs suggest that because the parties have not yet initiated discovery in either forum, Mylan would not be prejudiced. See Motion at 12. But Mylan has appeared in this action and asserted counterclaims upon which it will bear the burden at trial. D.I. 12. Mylan will likely serve discovery first in this forum, and be left without a remedy in the event of a dispute. *Novartis*, No. 1:14-cv-106, Order (D.I. 47) at 15. Mylan has not made a general appearance in the District of New Jersey and therefore the discovery process cannot start until the issue of jurisdiction is resolved.⁵ Even assuming the New Jersey court were eventually determined to have jurisdiction (which it does not), Mylan would have to “start over” in the discovery process vis-a-vis its invalidity claims. Accordingly, this is not a satisfactory course and would in fact result in greater prejudice to Mylan.

⁵ District of New Jersey local rules mandate that the court’s initial scheduling conference be set “within 60 days of filing an initial answer.” New Jersey L. Civ. R. 16.1(a)(1). Because Mylan has not answered yet, the first-filed court is unlikely to schedule an initial conference. Neither party can propound discovery until there is a conference by the parties, and the court will not schedule that conference until it the pleadings are completed. Fed. Rule Civ. P. 26(d)(1). Thus, Mylan is barred from pursuing discovery in the New Jersey Action until after the jurisdictional dispute is resolved.

Finally, Plaintiffs' discussion of Mylan's prior litigation history in New Jersey is irrelevant. That Mylan has elected not to contest personal jurisdiction in isolated litigations prior to the *Daimler* decision has no bearing on its jurisdictional challenge now that the Supreme Court has significantly narrowed the scope of personal jurisdiction over out-of-state corporate defendants. The proper inquiry is whether Mylan will be prejudiced if it is hampered from obtaining discovery and otherwise pursuing resolution of the dispute. For the reasons outlined above, the answer is unquestionably that Mylan will suffer great prejudice if this action is stayed.

IV. CONCLUSION

For the foregoing reasons, Mylan respectfully requests that this Court deny Plaintiffs' Motion to stay this action.

July 31, 2015

STEPTOE & JOHNSON PLLC

By: /s/ Christopher A. Lauderman
Gordon H. Copland (WV Bar #828)
gordon.copland@steptoe-johnson.com
William J. O'Brien (WV Bar #10549)
william.obrien@steptoe-johnson.com
Christopher A. Lauderman (WV Bar # 11136)
chris.lauderman@steptoe-johnson.com
400 White Oaks Boulevard
Bridgeport, WV 26330
Telephone: (304)933-800
Facsimile: (304)933-8183

Of Counsel:

Tung-On Kong (tkong@wsgr.com)
WILSON SONSINI GOODRICH & ROSATI
One Market Street
Spear Tower, Suite 3300
San Francisco, California 94105
(415) 947-2000

Dennis Gregory (dgregory@wsgr.com)

WILSON SONSINI GOODRICH & ROSATI

1301 Avenue of the Americas

New York, New York 10019

(212) 999-5800

Mary Procaccio-Flowers (mprocaccioflowers@wsgr.com)

Nancy Zhang (nzhang@wsgr.com)

WILSON SONSINI GOODRICH & ROSATI

650 Page Mill Rd.

Palo Alto, California 94304

(650) 493-9300

Attorneys for Defendant Mylan Pharmaceuticals Inc.

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
AT CLARKSBURG**

TAKEDA GMBH, ASTRAZENECA
PHARMACEUTICALS LP, and
ASTRAZENECA UK LIMITED,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS INC.,

Defendant.

C.A. No. 1:15-CV-00093-IMK

CERTIFICATE OF SERVICE

I certify that on the 31st day of July 2015, I electronically filed “Mylan Pharmaceuticals Inc.’s Opposition to Plaintiffs’ Motion to Stay” with the Clerk of the Court using the CM/ECF system, which will send notice of the same to the following counsel of record:

James F. Companion
Yolanda G. Lambert
**SCHRADER, BYRD & COMPANION, PLLC -
WHEELING**
The Maxwell Centre, Suite 500
32 - 20th Street
Wheeling, WV 26003
jfc@schraderlaw.com
ygl@schraderlaw.com

Amy K. Wigmore
Tracey C. Allen
**WILMER CUTLER PICKERING HALE AND
DORR LLP**
1875 Pennsylvania Avenue
Washington, DC 20006
amy.wigmore@wilmerhale.com
tracey.allen@wilmerhale.com

/s/ Christopher A. Lauderman
Gordon H. Copland (WV Bar #828)
gordon.copland@steptoe-johnson.com
William J. O’Brien (WV Bar #10549)
william.obrien@steptoe-johnson.com
Christopher A. Lauderman (WV Bar #11136)
chris.lauderman@steptoe-johnson.com
STEPTOE & JOHNSON PLLC
400 White Oaks Boulevard
Bridgeport, WV 26330
Telephone: (304) 933-8000
Facsimile: (304) 933-8183
Attorneys for Defendant